

## **EXHIBIT 5, Tab E**

**E**

# **APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS**

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The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2003.

## **24<sup>th</sup> EDITION**



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF PHARMACEUTICAL SCIENCE  
OFFICE OF GENERIC DRUGS**

**2004**

## PRESCRIPTION DRUG PRODUCT LIST

3-213

LAMOTRIGINETABLET; ORAL  
LAMICTAL

GLAXOSMITHKLINE

25MG

100MG

150MG

+

200MG

TABLET, CHEWABLE; ORAL  
LAMICTAL CD

GLAXOSMITHKLINE

2MG

5MG

+

25MG

LANSOPRAZOLECAPSULE, DELAYED REL PELLETS; ORAL  
PREVACID

TAP PHARM

15MG

+

30MG

FOR SUSPENSION, EXTENDED RELEASE; ORAL  
PREVACID

TAP PHARM

15MG/PACKET

+

30MG/PACKET

TABLET, ORALLY DISINTEGRATING; ORAL  
PREVACID

TAP PHARM

15MG

+

30MG

LANSOPRAZOLE; \*MULTIPLE\*SEE AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLEN20241 005  
DEC 27, 1994  
N20241 001  
DEC 27, 1994  
N20241 002  
DEC 27, 1994  
N20241 003  
DEC 27, 1994N20764 004  
SEP 08, 2000  
N20764 001  
AUG 24, 1998  
N20764 002  
AUG 24, 1998N20406 001  
MAY 10, 1995  
N20406 002  
MAY 10, 1995N21281 001  
MAY 03, 2001  
N21281 002  
MAY 03, 2001N21428 001  
AUG 30, 2002  
N21428 002  
AUG 30, 2002LANSOPRAZOLE; NAPROXENCAPSULE, DELAYED REL PELLETS, TABLET; ORAL  
NAPRAPAC 250 (COPACKAGED)

TAP PHARM

15MG,N/A;N/A,250MG

NAPRAPAC 375 (COPACKAGED)

TAP PHARM

15MG,N/A;N/A,375MG

NAPRAPAC 500 (COPACKAGED)

+ TAP PHARM

15MG,N/A;N/A,500MG

N21507 002  
NOV 14, 2003N21507 003  
NOV 14, 2003N21507 004  
NOV 14, 2003LATANOPROSTSOLUTION/DROPS; OPHTHALMIC  
XALATAN

+ PHARMACIA AND UPJOHN 0.005%

N20597 001  
JUN 05, 1996LEFLUNOMIDE

TABLET; ORAL

ARAVA

AVENTIS PHARMS

10MG

+

20MG

N20905 001  
SEP 10, 1998  
N20905 002  
SEP 10, 1998LEPIRUDIN

INJECTABLE; INJECTION

REFLUDAN

+ BERLEX LABS

50MG/VIAL

N20807 001  
MAR 06, 1998LETROZOLE

TABLET; ORAL

FEMARA

+ NOVARTIS

2.5MG

N20726 001  
JUL 25, 1997

## DISCONTINUED DRUG PRODUCT LIST

6-74

KETOROLAC TROMETHAMINE  
INJECTABLE

KETOROLAC TROMETHAMINE 30MG/ML N75230

## TABLET

KETOROLAC TROMETHAMINE 10MG N74780

KRYPTON, KR-81M

## GAS

MPI KRYPTON 81M GAS GENERATOR N/A N18088

LABETALOL HYDROCHLORIDE

## INJECTABLE

LABETALOL HCL 5MG/ML N75355

## TABLET

LABETALOL HCL 100MG N75223

LABETALOL HCL 200MG N75223

LABETALOL HCL 300MG N75223

NORMODYNE 400MG N18687

TRANDATE 400MG N18716

LACTULOSE

## SOLUTION

CEPHULAC 10GM/15ML N17657

CHRONULAC 10GM/15ML N17884

DUPHALAC 10GM/15ML N72372

GENERLAC 10GM/15ML N71842

LACTULOSE 10GM/15ML N71841

LACTULOSE 10GM/15ML N72029

LACTULOSE 10GM/15ML N73160

LACTULOSE 10GM/15ML N73580

LACTULOSE 10GM/15ML N17906

PORTALAC 10GM/15ML N72374

LAMOTRIGINE

## TABLET

LAMICTAL 250MG N20241

LAMICTAL 50MG N20241

## TABLET, CHEWABLE

LAMICTAL CD 100MG N20764

LEFLUNOMIDE

## TABLET

ARAVA 100MG N20905

LEUCOVORIN CALCIUM

## FOR SOLUTION

LEUCOVORIN CALCIUM EQ 60MG BASE/VIAL N08107

## INJECTABLE

LEUCOVORIN CALCIUM EQ 3MG BASE/ML N88352

LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL N88353

LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL N88938

LEUCOVORIN CALCIUM

## INJECTABLE

LEUCOVORIN CALCIUM EQ 100MG BASE/VIAL N81224

LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL N70480

LEUCOVORIN CALCIUM EQ 3MG BASE/ML N08107

WELLCOVORIN EQ 100MG BASE/VIAL N89834

WELLCOVORIN EQ 25MG BASE/VIAL N89833

WELLCOVORIN EQ 50MG BASE/VIAL N89465

WELLCOVORIN EQ 5MG BASE/ML N87439

## TABLET

LEUCOVORIN CALCIUM EQ 25MG BASE N71598

LEUCOVORIN CALCIUM EQ 5MG BASE N71600

WELLCOVORIN EQ 25MG BASE N18342

WELLCOVORIN EQ 5MG BASE N18342

LEUPROLIDE ACETATE

## INJECTABLE

LUPRON DEPOT-PED 3.75MG/VIAL;7.5MG/VIAL N20263

LUPRON DEPOT-PED 7.5MG/VIAL;7.5MG/VIAL N20263

LEVALLORPHAN TARTRATE

## INJECTABLE

LORFAN 1MG/ML N10423

LEVAMISOLE HYDROCHLORIDE

## TABLET

ERGAMISOL EQ 50MG BASE N20035

LEVOBETAXOLOL HYDROCHLORIDE

## SUSPENSION/DROPS

BETAXON EQ 0.5% BASE N21114

LEVOCARNITINE

## SOLUTION

CARNITOR 1GM/10ML N18948

LEVODOPA

## CAPSULE

BENDOPA 100MG N16948

BENDOPA 250MG N16948

BENDOPA 500MG N16948

DOPAR 100MG N16913

DOPAR 250MG N16913

DOPAR 500MG N16913

LARODOPA 100MG N16912

LARODOPA 250MG N16912

LARODOPA 500MG N16912

## TABLET

DOPAR 250MG N16913

DOPAR 500MG N16913

LARODOPA 100MG N16912